510(k) Summary

Date Prepared (21 CFR 807.92(a)(1): September 8, 2010

MAY 18 2011

Owner's Name (21 CFR 807.92(a)(1):

	Vision-Sciences, Inc.
Address:	40 Ramland Road South Orangeburg, NY 10962
Telephone Number:	(845) 365-0600
Fax Number:	(845) 365-0620
Contact Person:	Lillian Quintero; Director QA/RA

Trade Name, Common Name, Classification (21 CFR 807.92(a)(2))

Subject Device Name:	Flexible ENT-5000 Scopes with Digital Video Processor and Disposable EndoSheath® Technology
Common/Usual Name:	Flexible Video Endoscope with Sheath and Video Processor
Product Codes:	EOB, HRX
FDA Regulations:	21CFR874.4760, 21CFR888.1100
Device Classification:	Class II

Predicate Device Names (21 CFR 807.92(a)(3))

Modified Flexible ENT Scopes with Digital Video Processor and Disposable EndoSheath® Technology (K072073)

Avis Surgical Technologies, Inc.: C-MOR Visualization System (K093717)

Biomet InnerVue™ Diagnostic Scope System (K072879)

Smith & Nephew Arthroscope (K043395)

SpineView SpineVu Endoscopic Spine System (SESS™) and SpineVu MiniScope (K081051)

Common/Usual Name:	Flexible video endoscopes with sheaths and accessories
Product Codes:	EOB, HRX
FDA Regulations:	21CFR874.4760, 21CFR888.1100
Device Classification:	Class II
Premarket Notification:	K072073/K093717/K072879/K043395/K081051

Device Description

The VSI endoscopes are flexible endoscopes with connections to a video processor and display monitor. The EndoSheath® Techology for the ENT-5000 are optional, sterile, single-use protective sheath systems, with or without a working channel, that are intended to cover the entire insertion tube of the videoscope. The digital video processors are used with the flexible videoscopes for image visualization and capture.

Intended Use

The flexible ENT Videoscope with EndoSheath® Technology is intended for use in flexible endoscopic examination of the upper airway, vocal cords and/or nasal passages; and for use in diagnostic arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

Technological Characteristics

Vision Sciences believes that the subject device is substantially equivalent to both the Vision Sciences' predicate device, as well as those of other manufacturers, as outlined in this submission. The subject device has very similar functionality and indications as the predicate devices.

Performance Testing

The subject device has been subjected to and passed electrical safety, thermal, and EMC testing requirements. The patient contact materials in the endoscope are identical to the materials used in predicate device Vision Sciences' ENT-5000 (K072073).

Conclusion

Based on this request for additional indications for use, and the comparison to predicate devices, the VSI flexible video endoscopes with digital video processor and disposable EndoSheath® Technology have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vision-Sciences, Inc.
% Ms. Lillian Quintero
40 Ramland Road, South
Orangeburg, New York 10962

MAY 18 2011

Re: K102733
Trade/Device Name: Flexible ENT-5000 Video ENT Scope with Video Processor and EndoSheath®
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, HRX, EOB
Dated: April 27, 2011
Received: April 29, 2011

Dear Ms. Quintero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K102733

Device Name: Flexible ENT-5000 Video ENT Scope with Video Processor and EndoSheath® Technology

Indications for Use: The flexible ENT-5000 Video ENT Scope with EndoSheath® Technology is intended for use in flexible endoscopic examination of the upper airway, vocal cords and/or nasal passages; and for use in diagnostic arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

The digital video processor is intended for use with the VSI flexible video scope.

Prescription Use __X___ OR Over-the -Counter Use ____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102733